

DENT
GEOSOFT

ESTÜS

USER'S MANUAL

**ESTUS DENTAL COMPLEX:
DEVICE FOR ROOT CANALS
OBTURATION**

ESTUS PACK-FILL



Congratulations!

! On buying the device, be sure to check the delivery set, presence and correctness of the Quality Warranty Card filling, the acceptance certificate and product selling marks.

! Please, thoroughly read the user's guide before using the device. Keep the User's guide for future use.

! Please, address to the manufacturer if you have some questions when using the device.

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1. GENERAL INFORMATION

1.1. Intended use: Device for root canal obturation «Estus Pack-Fill» is part of the dental complex "Estus", intended for carrying out procedures in the field of dentistry.

This device is designed for the tooth root canals 3D obturation by the heated gutta-percha on the obturation steps: “DownPack” and “BackFill”.

“Estus Pack-Fill” consists of two functional handpieces:

1. Functional handpiece “Estus Pack” is for:

- heating, vertical condensation of the dental gutta-percha and cutting the gutta-percha tips in the root canal on the obturation step “DownPack”;
- thermal activation of the irrigating solutions.

2. Functional handpiece “Estus Fill” is for the heating and the following injection of the heated gutta-percha into the root canal by the special injector needle on the step of obturation “BackFill”.

1.2. Indication for use: Obturation of root canals during endodontic treatment.

The manufacturer is not responsible for any dangerous situation while using the device for purposes other than that intended.

1.3. Application field: The device is for use ONLY in medical facilities.

1.4. Potential users: ONLY the licensed dentists (qualified specialist in the field of endodontics).

1.5. Contraindications: Do not use in the patients sensitive to the natural latex.

1.6. Adverse reactions: Using the device in the patients sensitive to the natural latex could cause allergic reaction in the form of the face edema, lips or eyes swelling, and also difficulty breathing. In any of these cases it is recommended for a patient to apply to a doctor immediately.

1.7. Contact type with a patient: Short invasive contact through the oral cavity.

1.8. Operating principal:


1. “Estus Pack” handpiece: Fast heating of the thermopluggger tip by the heating system “handpiece - thermopluggger” to the temperature of gutta-percha softening. Then stabilization of the thermopluggger working temperature during the whole obturation process thanks to the temperature sensor built in the thermopluggger. Inserting the heated thermopluggger into the root canal for softening and obturating the gutta-percha in the canal.

2. “Estus Fill” handpiece: Fast heating of the gutta-percha obturator in a locked volume of the heater liner for the gutta-percha softening, its further pressing out by the rod with the gasket into the root canal. Stabilization of the thermopluggger working temperature during the whole obturation process thanks to the temperature sensor built in the heater. Maintaining low temperature on the outer surface of the device heating element due to its highly efficient thermal isolation.

1.9. Operating abilities:

1. “Estus Pack” handpiece:

- Four working modes:

- “CUT” - the mode of the gutta-percha tips cutting.
- “PACK” - the mode of the gutta-percha condensation.
- “PACK+  ” - the mode of the gutta-percha condensation with the additional vibration function, which allows to fill the canal more full and even, minimizing the air bubbles in the condensed gutta-percha, reducing the risk of complications in a patient after endodontic treatment.
- “MIX” - the mode of the irrigating solutions thermal activation with the vibration function.
- Automatic shutdown of the thermopluggger heating after a certain period of time set in each mode.
- Thermopluggger correct functioning monitoring.

2. “Estus Fill” handpiece :

- Gutta-percha heating in the heater liner up to set working temperature.
- Monitoring and indication of all phases of gutta-percha heating and cooling.
- Monitoring and indication of gutta-percha residue in the heater liner.
- Two modes of the heated gutta-percha extrusion:
 - dose - for the “apical plug” forming one-third and adding small doses of heated gutta-percha;
 - continuous - for filling the two thirds of the canal.
- Three levels of heated gutta-percha feed rate - «**H**igh», «**M**iddle», «**L**ow»

3. Common for both handpieces:

- Audio indication during the process and audio signal volume control.
- Power supply discharge indication.

- Power supply saving.

- The possibility of expanding “ESTUS PACK- FILL” functionality in terms of settings and displaying the values of its operating parameters when the device is operating as a part of the “Estus” dental complex together with the “Estus Multi”* main control unit.

** not included into the delivery set and should be purchased separately.*

1.10. Precautions and Warnings

! Use the product with the original “Geosoft Dent” accessories only (*see section 3*).

! Do not disassemble or modify the product. **Violation of the device integrity cancels the warranty.**

! Avoid letting any liquid inside the product’s housing.

! Do not use the device close to flammable agents. The device is not suitable for use in presence of flammable anesthetic agents with air, oxygen or nitric oxide.

! Use sterile and disinfected parts and accessories of the device only. Sterilization and disinfection must be conducted directly before the first use and between each patient use to avoid cross infection. (*detailed see section 7*).

! To avoid thermal burns when working with the “Estus Pack” handpiece, do not touch the thermopluggger while it is heating. Avoid contact the hot thermopluggger with the patient’s lips and oral mucosa.

! For safety reasons, do not work in the root canal with a heated thermopluggger for more than 12 seconds in a row.

! In order to avoid overheating and failure of the “Estus Pack” handpiece control unit and / or thermopluggger, do not reactivate the heating mode without waiting until the thermopluggger cooling, more than 10 times in a row.

! To avoid thermal burns replace thermopluggers only after its complete cooling.


! Be attentive working with “ESTUS PACK-FILL”: gutta-percha obturators include natural latex, which could cause allergic reaction.

! To avoid thermal burns when working with the “Estus Fill” handpiece, do not touch the injector needle while it is heating. Avoid contact the hot needle with the patient’s lips and oral mucosa. Replace the needle only after its complete cooling.

! To avoid the injector needle breakage at the necessity of its curving be sure to use the special tool for the injector needles curving from the device delivery set. Do not over press on the injector needles during the operation.

! When working in the patient's oral cavity, use a rubber dam.

! This device requires special measures application for electromagnetic capability (EMC) and should be installed and put into operation accordingly with the information in the Appendix of the User’s Manual. It includes the requirement not to use the device close to daylight lamps, radio transmitting equipment and remote controls.

! The device dysfunction is possible if used in electromagnetic interference (EMI) area. Do not use the device close to the electromagnetic equipment. This equipment is usually marked by the sign 

! Do not use the device jointly with the other equipment or as a part of the equipment, not included into the manufacturer’s product list.

! Do not use the accessories, adapters and cables, different from the listed below. It can direct to the emission interference increase or reduce interference immunity of the device. The Manufacturer guarantees electromagnetic compatibility of the following accessories: *the charger cable of the maximal length 1.8 m.*

! The device operates normally at a temperature of 10-35 ° C, relative humidity of air not more than 80%, atmospheric pressure (101 ± 3) kPa. Any violation of these restrictions may cause the device error.

2. DELIVERY SET

Delivery set variants are in the table 1.

Table 1

	The device element	Quantity, pcs in the delivery set variant		
		Pack	Fill	Pack-Fill
1	Control unit “Estus Pack”	1	-	1
2	Control unit “Estus Fill”	-	1	1
3	Battery unit	1	1	2
4	Thermoplugger “S” (02/45)	-	-	1
5	Thermoplugger “M” (04/50)	1	-	1
6	Thermoplugger “L” (08/55)	-	-	1
7	Heater “Estus Fill”	-	1	1
8	Injector needle (gauge 23G)	-	1	1
9	Injector needle (gauge 25G)	-	1	1
10	Gutta-percha obturators	-	10	10
11	Cleaning and level measuring tool gutta-percha in a heater	-	1	1
12	Multi-functional wrench for injector needle	-	1	1
13	Stand “Estus Two-B”	-	-	1
14	Stand “Estus One-B”	1*	1*	-

Table 1 continued

	The device element	Quantity, pcs in the delivery set variant		
		Pack	Fill	Pack-Fill
15	Charging stand “Estus Energy-S”	1*	1*	-
16	Charging stand “Estus Energy-D”	-	-	1
17	Charger cable USB - USBB	1*	1*	1
18	Power adapter (USB-socket) 1A	1*	1*	-
19	Power adapter (USB-socket) 2A	-	-	1
20	User’s manual	1	1	1
21	Warranty Card “Estus Pack-Fill”	1	1	1
22	Warranty Card “Estus Energy-S/D”	1*	1*	1
23	Package	1	1	1

** The components are supplied only in the Plus package*

3. ACCESSORIES

Thermoplugger “S” GE99.142.000

Thermoplugger for heating and condensing gutta-percha in the apical area (one-third) of the canal.

Size 02/ 45

Used with the “Estus Pack” handpiece



Thermoplugger “M” GE99.144.000

Thermoplugger for heating and condensing gutta-percha in the two-thirds of the canal

Size 04/ 50

Used with the “Estus Pack” handpiece



Thermoplugger “L” GE99.146.000

Thermoplugger for the gutta-percha tips cutting.

Size 08/ 55

Used with the “Estus Pack” handpiece



Heater “ESTUS”

GE99.213.000

Optional sterilizable heater for the “Estus Fill” handpiece.

Sterilization is in autoclave.



Battery unit GE99.205.000

Optional battery unit for the “Estus Pack” and the “Estus Fill” handpieces (2x3.7 V, 800mAh)





Gutta-percha obturators (100 pcs).

GE99.188.000. Gutta-percha obturators for the “Estus Fill” handpiece.

Type: Soft, Medium, Hard



Injector needles (4 pcs)

(gauge 23G) GE99.186.000

Injector needles for the “Estus Fill” handpiece (gauge 23G)



Injector needles (4 pcs)

(gauge 25G) GE99.187.000

Injector needles for the “Estus Fill” handpiece (gauge 25G)



Tools kit for the “Estus Fill” handpiece

GE99.251.000

The kit content:

- Multi-functional wrench for injector needle.
- Sterilization is in autoclave.
- Cleaning and level measuring tool gutta-percha in a heater



Spare gaskets for the “Estus Fill” handpiece (3 pcs) GE99.201.000

Spare gaskets for the “Estus Fill” handpiece



Power adapter (USB-socket) 1A

GE99.005.00P

Model: Robiton USB1000/White

Input voltage - (100-240) V, ~50/60 Hz

Output voltage - 5 V; 1A.

Control unit “Estus Multi” GE28.000.000

External apex locator and control unit for the extended setting and indication of the working parameters for the “Estus Pack” and “Estus Fill” handpieces.

**Charging stand “Estus Energy-S” GE42.000.000**

One-port charging stand to charge the battery unit for the “Estus Pack” and the “Estus Fill” handpieces.

**Charging stand “Estus Energy-D” GE39.000.000**

Double-port charging stand to charge two battery units for the “Estus Pack” and the “Estus Fill” handpieces.

**Stand “Estus One-B” GE99.208.000**

Single stand for the “Estus Pack” and the “Estus Fill” handpieces.

**Stand “Estus Two-B” GE99.209.000**

Double stand for the “Estus Pack” and the “Estus Fill” handpieces.

**Power adapter (USB-socket) 2A
GE99.006.00P**

Model: Robiton USB2100

Input voltage - (100-240) V, ~50/60 Hz

Output voltage - 5 V; 2A.





Plugger SSG Plugger #1 - #2

Manual endodontic plugger for root canal obturation (Geosoft Endoline).

1 - .02 / ISO 50,

2 - .02 / ISO 60



Plugger SSG Plugger #3 - #4

Manual endodontic plugger for root canal obturation (Geosoft Endoline).

3 - .02 / ISO 80,

4 - .02 / ISO 100



Charger cable USB-USBB

GE99.001.00P

Cable for charging stand "Estus Energy-S" / "Estus Energy-D". Length 1.8 m

! Accessories are delivered separately, additionally paid

4. “ESTUS PACK - FILL” APPEARANCE

“Estus Pack - Fill” appearance is on the figure 1, including:

A/B. “Estus Fill” /“Estus Pack” handpiece:

1,1' - Control unit.

2 - Heater.

3 - Injector needle.

4 - Thermoplugger.

5,5' - Removable battery unit.

6,6' - Control ring switch (*see table1*).

7,7' - “STATUS” indicator (*see table2*).

8 - LED scale of 5 indicators for displaying the level of gutta-percha residues in the heater liner of the “Estus Fill” handpiece and the selected gutta-percha feed rate;

9 - LED scale of the 4 indicators to display the chosen working mode of the “Estus Pack” handpiece.

10, 10' - Discharge indicator of the removable battery unit.

C/D. Charging stand “Estus Energy-S” / “Estus Energy-D”:

11, 11' - Charging socket.

12, 12' - Charge indicator;

13, 13' - Socket USB-B for the charger cable.

E. Cleaning and level measuring tool gutta-percha in a heater

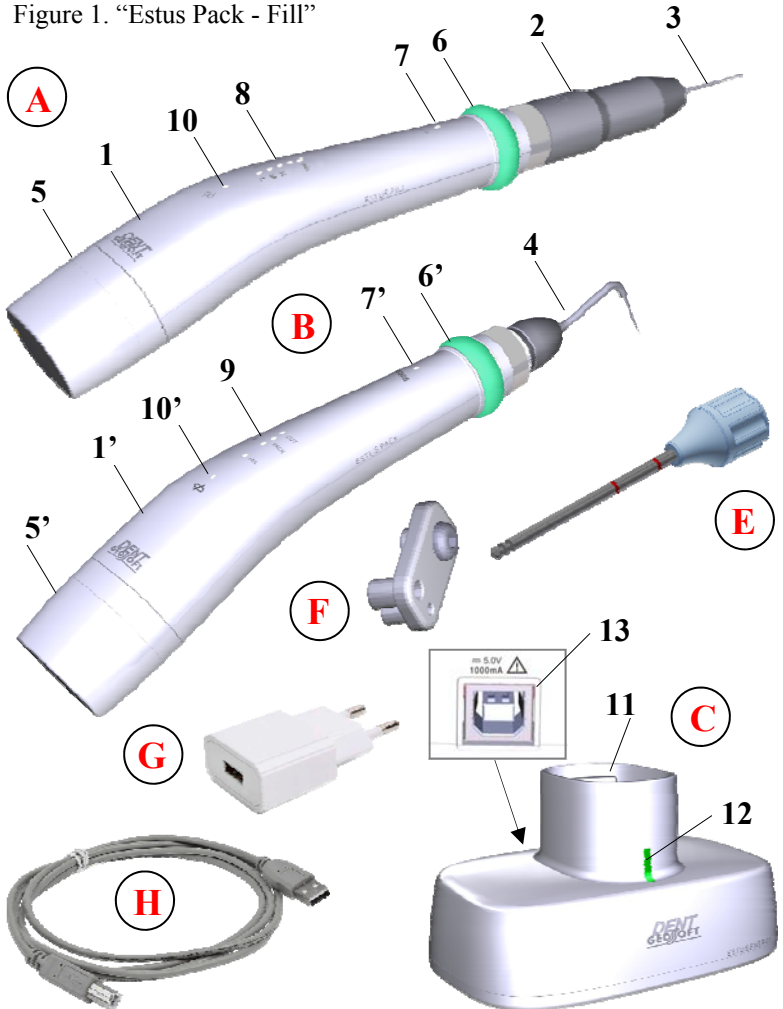
F. Multifunctional wrench for an injector needle.

G. Power adapter (USB-socket).

H. Charger cable USB- USBB.

I/J. Stand ”Estus Two-B” / “Estus One-B” for the handpieces.

Figure 1. "Estus Pack - Fill"



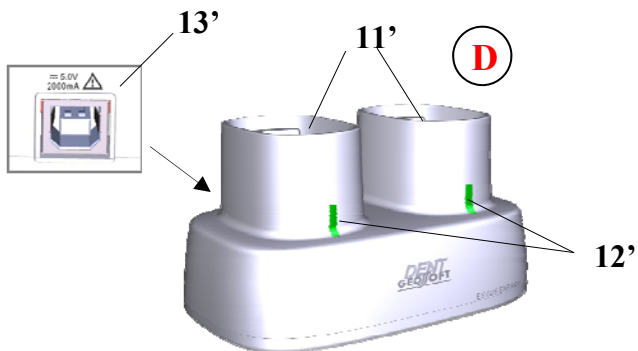
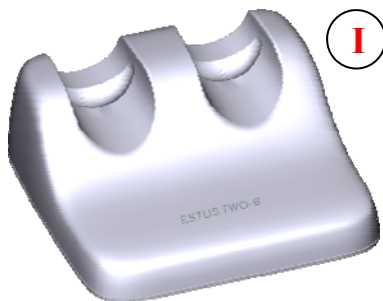


Table 1. Variants of using the ring switch








	Power supply	Press ring switch	Result	
			Estus Pack	Estus Fill
	OFF	1 time	Power on	
		holding up to 10 sec.	Volume adjustment	
		holding > 20 sec.	Pair creating mode activation	
	ON	1 time	On / Off in the heating mode	Switching on the heating mode.
		1 time with holding till switching off.		-
		1 time in the readiness mode	-	Activation of the DOSE gutta-percha injection mode
		Holding in the readiness mode	-	Activation of the CONTINUOUS gutta-percha injection mode
		2 times	The working mode choosing	Selection of the gutta-percha feed rate
		2 times with holding		
		3 times	Power off	
		3 times with holding	Return to the factory settings	

Table 2. Indicator “STATUS” variants

Indication STATUS color		Meaning
 STATUS	WHITE	Temperature $\leq 50^{\circ}\text{C}$
 STATUS	WHITE blinking	Activation of the pair creation mode or a warning that the current settings are different from the factory settings (changed by the user).
 STATUS	ORANGE blinking	Process of heating to the working temperature
 STATUS	ORANGE	Readiness to work
 STATUS	LILAC blinking	Process of cooling to 50°C
 STATUS	RED blinking	Heating error (see section 9)

5. TECHNICAL SPECIFICATIONS

5.1. “Estus Pack” / “Estus Fill” handpieces:

- Power supply - Li-Po battery unit (2x3,7 V; 800 mAh).
- Electric shock protection - Device with the built-in power supply. Working part is of the type B
- The built-in radio module NF-03: frequency range - 2,4-2,525GHz, max output capacity - 7 dBm (0,00501W), cover range - up to 3m in the direct vision.
- Stand-by operating time to automatic switch off - $10 \pm 0,5$ minutes.

- Battery unit charging time - no more than 3 hours
- Battery resource - is not less than 300 recharges.
- The working area of the ring switch on the front side of the handpiece - 180°.
- The operating force of the ring switch - not more than 1N
- Audio indication parameters: audio frequency - from 1 to 6 kHz, volume level - not more than 70 dB.
- Dust and water protection rate - IP41.
- Service time of the device - 5 years.

Individual features of the “Estus Pack” handpiece:

- Working temperature in the mode:
 - of the gutta-percha cutting “CUT” - $150 \pm 10^{\circ}\text{C}$
 - of the gutta-percha condensing “PACK”* - $100 \pm 10^{\circ}\text{C}$
 - of the thermal activation of irrigant “MIX” - $50 \pm 5^{\circ}\text{C}$
- Stabilization accuracy of the working temperature - $\pm 2^{\circ}\text{C}$
- Thermopluggger heating time to the set working temperature – not more than 1.6 sec.
- Maximal duration of the thermopluggger heating cycle with the following automatic switch off in the mode:
 - of the gutta-percha cutting “CUT” - 7 sec.
 - of the gutta-percha condensing “PACK” - 12 sec.
 - of the thermal activation of irrigant “MIX” - 120 sec.
- Performance duration with the new fully charged battery unit - is not less than 500 heating cycles.
- Dimensions - $(207*33*43) \pm 3$ mm
- Weight - 80 ± 10 g

Individual features of the «Estus Fill» handpiece:

- Working temperature with the accuracy $\pm 5^{\circ}\text{C}$ (The temperature of the gutta-percha injection) - 180°C^*

- Stabilization accuracy of the working temperature- $\pm 10^{\circ}\text{C}$
- The time of heating from 20°C to 180°C - 15 ± 5 sec
- The time of extrusion of the one standard gutta-percha obturator with an accuracy of ± 10 seconds:
 - for the "High" feed rate - 30 sec
 - for the "Middle" feed rate - 65 sec
 - for the "Low" feed rate - 140 sec
- Working temperature keeping in stand-by mode - $3,0 \pm 0,1$ min.
- Performance duration with the new fully charged battery unit without boost charge - 13-15 heating cycles 3 min. each.
- The heater external surface temperature - is not more than 45°C
- The injector needle tip temperature - is not more than 75°C
- Dimensions - $(240*33*43) \pm 3$ mm
- Weight - 115 ± 10 g

** at the joint work of the handpieces with the "ESTUS MULTI" it is possible to control the working temperature:*

- in the range 80°C — 120°C with a step 10°C in the "PACK" mode for the "Estus Pack" handpiece and

- in the range 160°C — 200°C with a step 10°C for the "Estus Fill" handpiece.

5.2. Charging stand "Estus Energy-S":

- Power - 5V, 1A.
- Electric shock protection - the product is of the class II.
- Dust and water protection rate - IP41.
- Dimensions - $(87*56*49) \pm 3$ mm
- Weight - 145 ± 10 g
- Service time of the device - 5 years.

5.3. Power adapter (USB-socket) 1A

- Input voltage - (100-240) V, ~50/60 Hz
- Output voltage - 5 V; 1A.

5.4. Charging stand “Estus Energy-D”:

- Power - 5V, 2A;
- Electric shock protection - the product is of the class II.
- Dust and water protection rate - IP41.
- Dimensions- (87*56*49) ±3 mm
- Weight - 145±10 g
- Service time of the device - 5 years.

5.5. Power adapter (USB-socket) 2A

- Input voltage - (100-240) V, ~50/60 Hz
- Output voltage - 5 V; 2A.

5.6. Stand “Estus One-B”:

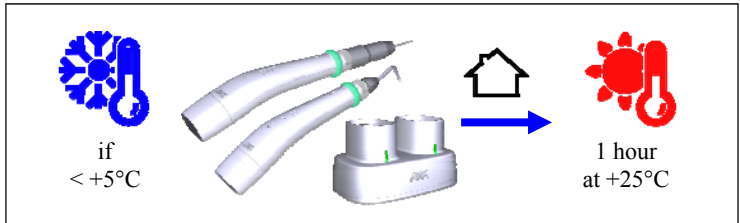
- Dimensions- (100*60*40) ±3 mm
- Weight - 132 ±10 g

5.7. Stand “Estus Two-B”:

- Dimensions- (102*100*40) ±3 mm
 - Weight - 155 ±10 g
-
-

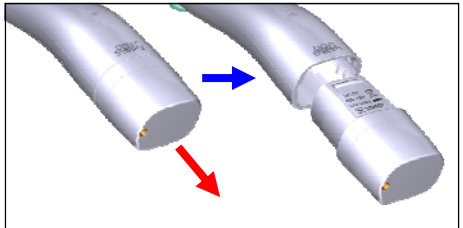
6. PREPARATORY STAGE AND WORKING PROCEDURE

After transporting the device at the temperature less than + 5°C, before use, keep it at the indoor temperature for 1 hour

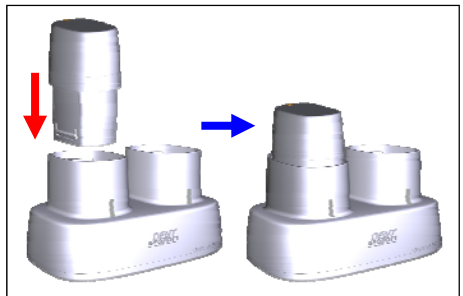


Step 1. Battery unit charging

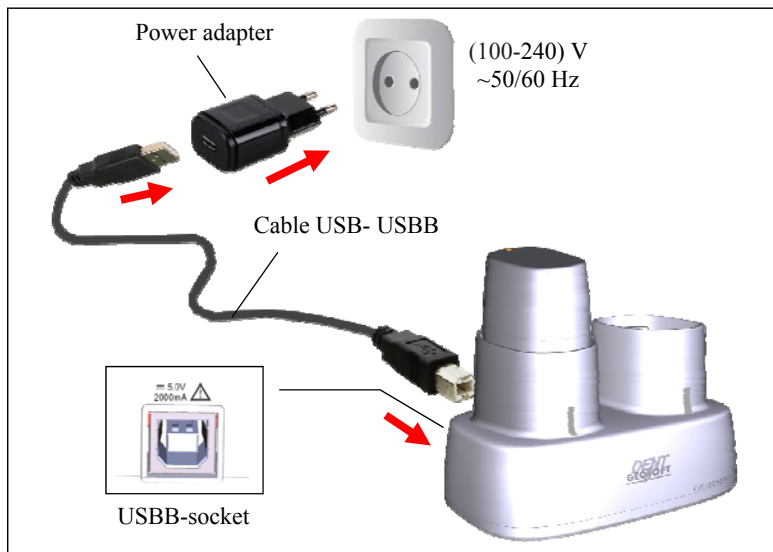
A) Disconnect the battery unit from the handpiece



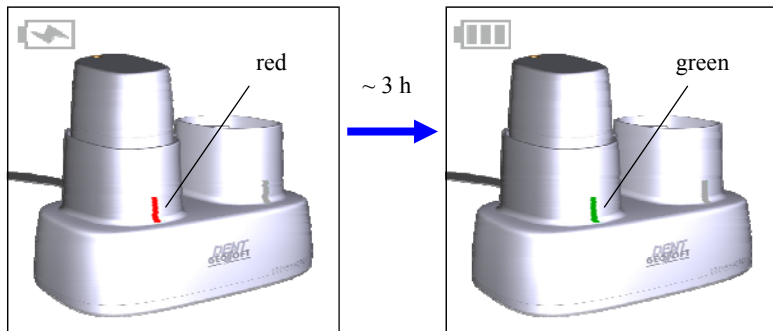
B) Put the battery unit into the charging socket of the charging stand “Estus Energy-S” (or into any vacant socket of the charging stand “Estus Energy - D”)



C) Connect the cable USB- USBB to the charging stand and the power adapter, then put the power adapter into the mains socket.



D) Wait till the battery is fully charged.



E) Put the charged battery unit out of the charging stand and connect it to the handpiece.

! *In the absence of the battery unit in the charging socket, the voltage is automatically disconnected from the charging stand terminals, ensuring complete electrical safety of the product. In spite of it, do not allow any liquids to get into the socket of the charging stand, and in a case of liquid getting to avoid the terminals corrosion, carefully wipe the charging socket of the charging stand with a napkin, after disconnecting the charge cable from the mains socket.*

📖 *Average charging time is about 3 hours, but it depends on the current charge level, the battery wear rate and outer temperature. The used battery performance and the charging process is shorter than the new ones. At the significant reduction of the battery performance time and/or charging time you should apply to the maintenance service for replacing the battery unit. (see section 3).*

The battery discharge indication:



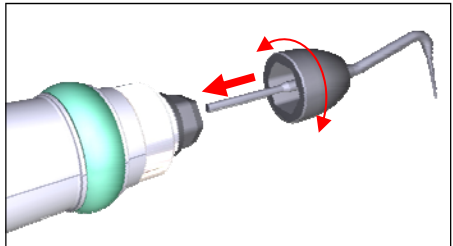
! *Charge the handpiece battery unit in a timely manner. Do not let the battery unit discharge completely.*

6.1. "ESTUS PACK" HANDPIECE OPERATION

Step 2. The thermoplunger installing

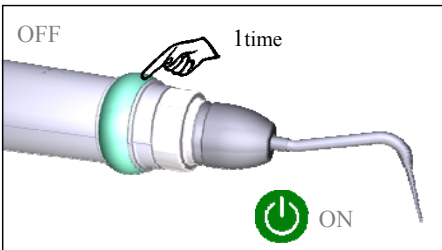
! *Be sure to sterilize the thermoplunger before first use and between each patient use (see section 7 «Sterilization and disinfection»).*

Choose the thermoplunger complying the current step of the treatment and also the convenient for work its fixing angle (one of the six fixed positions).



Install the thermoplunger into the handpiece socket.

Step 3. Power on




To switch the power on press the ring switch.

The indicator STATUS lights up **WHITE**



! *If the STATUS indicator flashes white three times when the device is powered on, it means that the settings are different from the factory settings (that is, they were changed by the user using "Estus Multi"). To return to the factory settings, see Step 10*

Step 4. Operating mode choosing

There are 4 operating modes in the handpiece - CUT, PACK, PACK+ , MIX.

The modes change one another cyclically.

Next to the chosen mode the white indicator lights up.

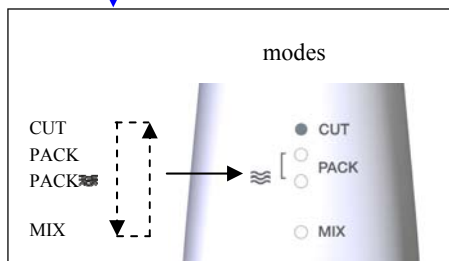
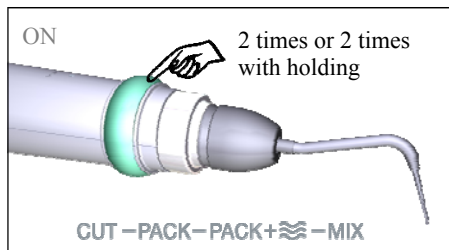



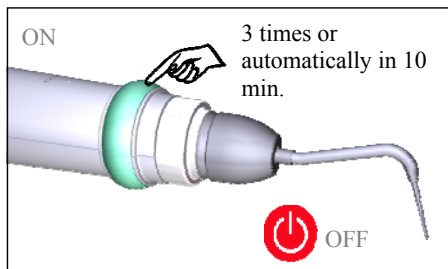
Table.3: Factory settings

Operating mode	Working temperature	Maximal duration of the heating cycle
CUT	150°C	7 sec
PACK /PACK+ 	100*°C	12 sec
MIX	50°C	120 sec

* the working temperature change is possible at the joint operation of the handpiece and “Estus Multi”.

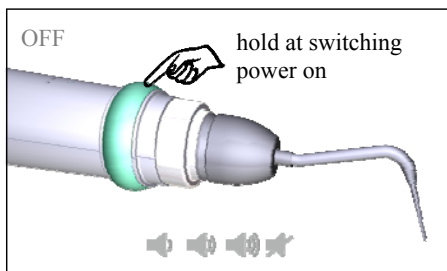
Step 5. Power off

Press the ring switch 3 times to switch the power off or the device is switched off automatically in 10 minutes.
All the indicators on the handpiece go out.



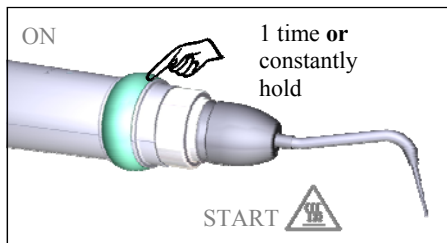
Step 6. Audio volume adjustment

The handpiece acoustic emitter has 4 volume levels: low, normal, high and off.



To select the required volume level hold the ring switch when switching the power on. Within ~10 sec. volume levels change one another cyclically.
To choose the required volume level stop pressing the ring switch.

Step 7. The handpiece operation - the heating mode switching on



Press the ring switch briefly **OR** press and hold to switch the heating mode on

During 1,0 - 1,6 sec. the thermoplugger is heating to the set working temperature. The STATUS indicator on the handpiece **blinks ORANGE**



STATUS

Start working after the STATUS indicator stops blinking and would constantly light **ORANGE**

! *To avoid thermal burns do not touch the heated thermoplugger, activate heating mode only in the root canal. At using the handpiece for the gutta-percha residue cutting off do not let the thermoplugger contact the patient mucosa.*

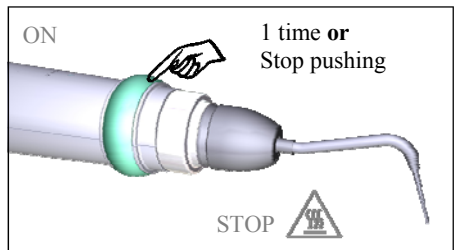
Step 8. Switching off the heating mode

The heating mode is switched off automatically in a definite period of time for every mode (see Step 4, table 3).

For the forced switching off the thermoplugger heating mode:

Press the ring switch briefly

OR stop pushing it at its holding.



! *For safety precautions the heated thermoplugger should not stay in the root canal more than 12 seconds at a row.*



After switching off the heating mode thermoplugger would start cooling. In the cooling process the STATUS indicator would **blinks LILAC**

At the achieving the safe temperature 50°C the STATUS indicator stops blinking and **constantly lights WHITE**



To avoid thermal burns do not touch the thermoplugger until its complete cooling.

Step 9. Thermoplugger conditions monitoring

Try to avoid the significant thermoplugger curving. Multiple significant thermoplugger curving could cause partial or complete electrical contact violation inside the thermoplugger. In this case, the thermoplugger loses its ability to heat up and it should be replaced.



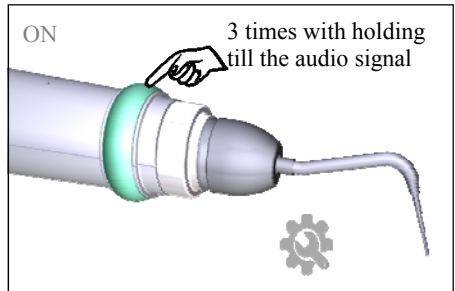
Failure of the thermoplugger would be automatically detected when trying to turn on the heating mode. In this case the STATUS indicator would **blink RED**. Additionally the blinking is accompanied by triple audio signal.

Step 10. Return to the factory settings

The handpiece settings could be changed at its joint work with the control unit “ESTUS MULTI”

To return to the factory settings (*see Step 4, table 3*):

When the device is powered on, press the ring switch 3 times and hold it about 5 seconds after the device power is turned off. Release the button when the audio signal has sounded.

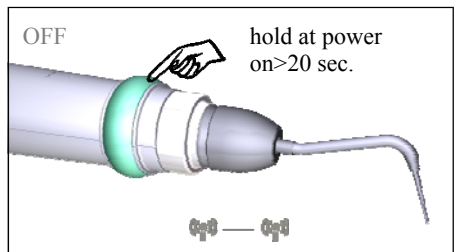


In this case, all settings will return to the factory values.

Step 11. Pair creation mode activation

For the joint work of the handpiece and the control unit “Estus Multi ” by radio channel it is necessary to create a pair. To activate pair creation mode on the handpiece:

Press and hold the ring switch at switching the power on. After 3 cycles of the audio signals with different intensity and 1 single audio signal (wait for 20 sec.) STATUS



indicator would constantly blink **WHITE**

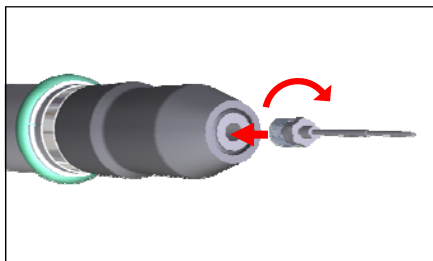


The pair creation further procedure of the handpiece with “Estus Multi” is described in the *User’s Manual “Estus Multi”* (p. 12.2. *Setting "Creating/Deleting pair" function*)

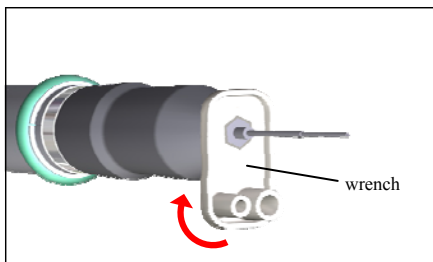
6.2. “ESTUS FILLL” HANDPIECE OPERATION

Step 2. Injector needle installing

! *Injector needles of other types and other manufacturers are not allowed. Use only Geosoft Dent injector needles (see section 3 “Accessories”).*



A) Screw the injector needle into the thread hole in the heater by turning the needle clockwise.




B) To avoid leakage of heated gutta-percha, gently tighten the needle with the multifunctional wrench.


Excessive force may cause the screw thread damage on the needle and / or heater.

! *Be sure to sterilize the injector needles before using. The needles could be sterilized separately or jointly with the heater (see section 7 “Sterilization and disinfection”).*

Step 3. Gutta-percha obturator installation


 *Using the gutta-percha obturators of other types and other manufacturers are not allowed. To avoid the gutta-percha under heating or overheating use only Geosoft Dent gutta-percha obturators (see section 3 “Accessories”).*

The gutta-percha obturator is placed in the heater liner. The heater is connected to the handpiece control unit with a detachable bayonet-type connection.


 *Be sure to sterilize the heater before using between each patient use (see section 7 “Sterilization and disinfection”).*

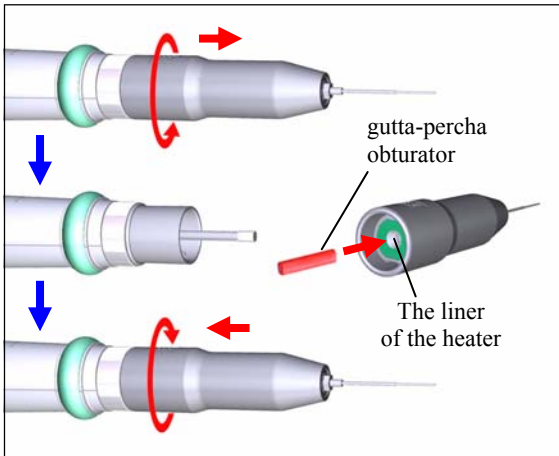
A) Disconnect the heater from the control unit, turning the heater counter clockwise.

B) Make sure that the heater liner is **empty or** that the gutta-percha residue in the liner does **not exceed 15%** of its initial length (*for more details, see Step 4.6*), then insert a new gutta-percha obturator into the liner.

 *It is forbidden to put the new obturator into the liner if the gutta-percha residue in the heater exceeds 15%. If the obturator replacement is necessary, take the gutta-percha residue out of the liner (see section 8.2)*

C) Install the heater on the control unit and turn it clockwise to fix

 *If, nevertheless, the new obturator was accidentally installed on top of the old one, and the heater fails to be fixed in the control unit, remove the gutta-percha residue from the liner (see section 8.2) and only then install the heater on the control unit.*



Never use force if the heater fails to be fixed in the handpiece control unit or, conversely, you cannot disconnect it from the control unit. If the problem takes place see section 9 “Troubleshooting”

Step 4. Definition of the gutta-percha residue level in the heater liner

There are two variants to define the gutta-percha residue level in the heater liner:

Variant 1: Manual

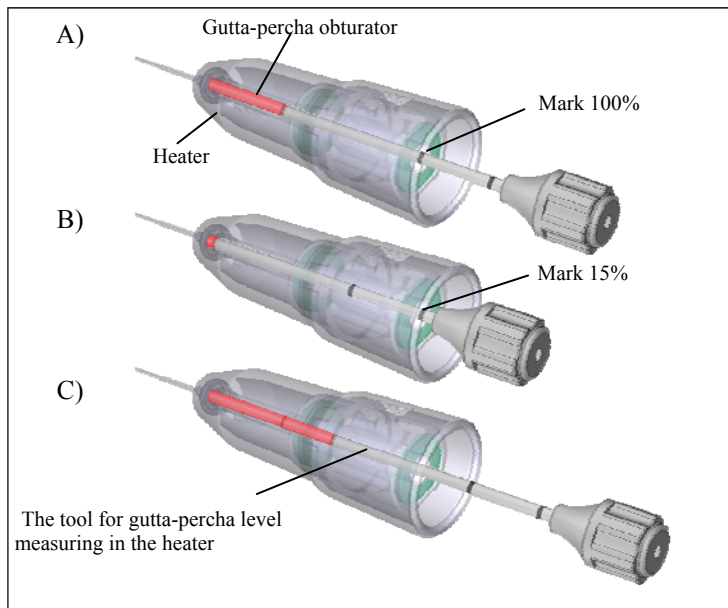
Put the tool for measuring the gutta-percha level into the heater liner to the stop.

A) If the device entered the heater liner to the mark of “100%” or

more, but the “15%” mark remained visible to the user - the gutta-percha level in the liner is sufficient to continue working.

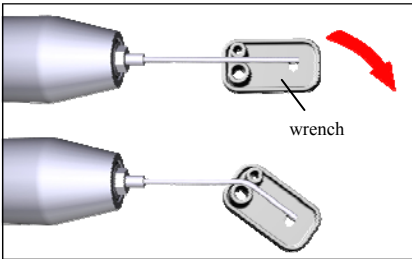
B) If the tool entered the heater liner to the mark of “15%” and more - it is necessary to put the new gutta-percha obturator into the liner (*see Step 3*) and then continue working.

C) If at the entering the tool into the heater liner both marks, “100%” and “15%”, are visible - it is necessary to remove the gutta-percha excess from the liner (*see p. 8.2*) and then continue working.



Variant 2: Electronic - see Step 6

Step 5. Injector needle curving

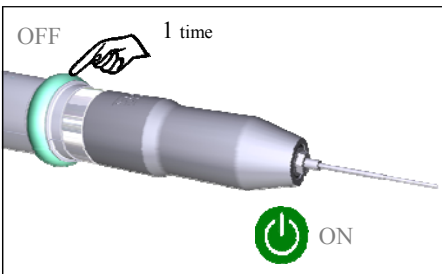


If necessary, use the multi-functional wrench to give the injector needle a smooth curvature so that the needle can extend about 5 mm beyond the working length of the canal.



To prevent fracture of the injector needle or blockage of its internal canal, do not bend the needle by hand.

Step 6. Power on. Moving the rod to the “readiness position”. Defining the level of gutta-percha residue.



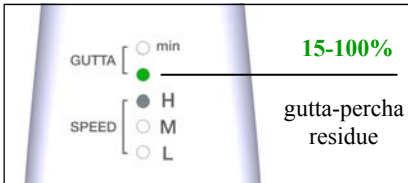
To switch the power on press the ring switch.

STATUS indicator lights up **WHITE**



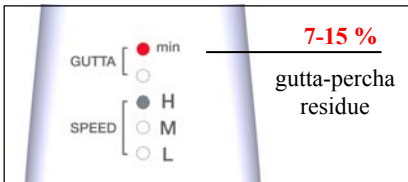
If the STATUS indicator flashes white three times when the device is powered on, it means that the settings are different from the factory settings (that is, they were changed by the user using "Estus Multi"). To return to the factory settings, see Step 13

The rod automatically moves forward until the gutta-percha level in the liner reaches the “readiness position”, and the gutta-percha residue in the heater liner is displayed on the LED scale:



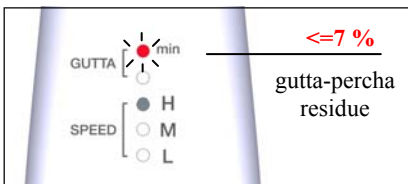
A) If the "GUTTA" indicator is **GREEN**, the remaining gutta-percha in the liner is enough to continue working (see Step 7)

B) If the "GUTTA" - "min" indicator is **RED**, the remaining gutta-percha does not exceed 15%.



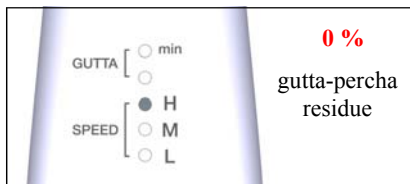
In this case, it is recommended to install a new gutta-percha obturator in the liner in advance (see Step 3) and only then continue working.

C) If the "GUTTA" - "min" indicator **FLASHES RED**, it means that the remaining gutta-percha in the liner is less than 7%.



In this case, to continue working, a new gutta-percha obturator must be installed in the liner.

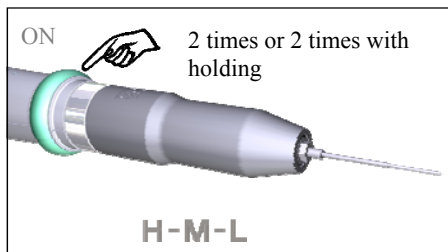
D) If the gutta-percha obturator is completely absent in the heater liner, the rod will automatically return to its original position, and both "GUTTA" indicators will be extinguished on the LED scale.



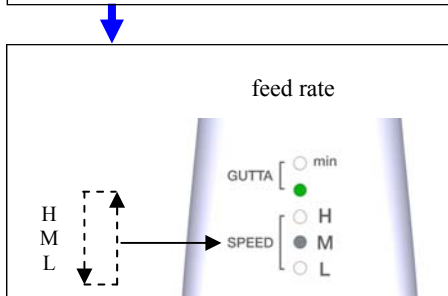
In this case, it is also **NECESSARY** to install a new gutta-percha obturator into the heater liner and only then continue working.

Step 7. Selecting the gutta-percha speed level delivery (feed rate)

The handpiece has 3 levels of gutta-percha feed rate - "H", "M" and "L".



To select the desired feed rate, press the button 2 times.



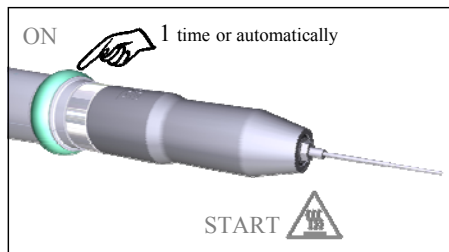
The parameter is changed cyclically. A white "SPEED" indicator lights up next to the name of the selected feed rate.

Table.4: Factory parameter settings:

Gutta-percha feed rate level		The time of extrusion of the whole gutta-percha obturator
«H»	High	30 sec.
«M»	Middle	65 sec.
«L»	Low	140 sec.

Step 8. Heating mode turning on

With the active indication of gutta-percha residues in the liner, press the ring switch to turn on **OR** the heating will start automatically if the temperature in the heater liner exceeds 100°C



At the same time, the gutta-percha will begin to heat up to operating temperature.



STATUS indicator on the handpiece **blinks ORANGE**



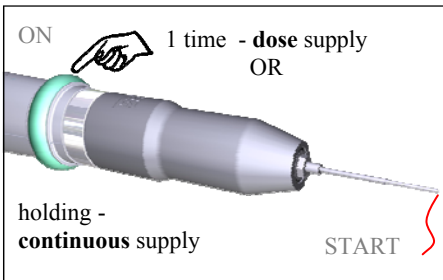
STATUS

Start working after the STATUS indicator stops blinking and is **constantly lit ORANGE**.



To avoid the thermal burns at the working with the device, do not touch the injector needle while the STATUS indicator lights up orange. Do not let the needle contact the patient's lips and mucosa. Replace the needle only after its complete cooling.

Step 9. Injection of the heated gutta-percha



A) Press the ring switch briefly to inject one dose of gutta-percha **OR** hold the ring switch to activate the continuous gutta-percha supply mode.

At using a new injector needle, gutta-percha extrudes out of the needle with a slight delay. Press out a small amount of gutta-percha, and then remove the excess gutta-percha from the tip of the needle before inserting it into the root canal.



After sterilization of the injector needle, the parameters of the remaining gutta-percha in the needle could be changed, and therefore, when re-using the sterilized needle, first press out all the remaining gutta-percha from it (about 3 cm) and only after that start working.

B) Gutta-percha is injected into the canal with significant pressure. In order to avoid the gutta-percha penetration out of the apical constriction of the canal, first create an apical plug in the canal. For it insert the needle into the root canal by about 2/3 of its working length

(in a zone of apical constriction) and briefly press the ring switch. A dose of the heated gutta-percha is injected into the canal.

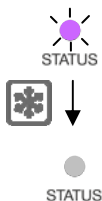
Take the needle out of the root canal and compact the dose of gutta-percha with the manual plugger (for example, «SSG Plugger» (Geosoft Endoline). Re-insert the needle into the canal, press and hold the ring switch. The gutta-percha continuous supply mode is activated. Slowly remove the needle from the canal until it is completely filled with gutta-percha. *(The alternative working techniques are possible).*

As it is squeezed out, the remaining amount of gutta-percha in the heater liner will be indicated on the LED scale of the handpiece in the form of a green or red indicator (for more information, see Step 6). When gutta-percha is completely pressed out of the liner, the rod is automatically returns to its initial position.

After the injection is stopped, the heater is in a working (heated) state for 3 minutes. During this time, to re-inject gutta-percha, press and hold the ring switch, additional waiting time for heating gutta-percha is not required.

Step 10. Turning off the heating mode - activating the cooling mode.

The heating mode is switched off **automatically in 3 minutes** after the last activation of the ring switch.

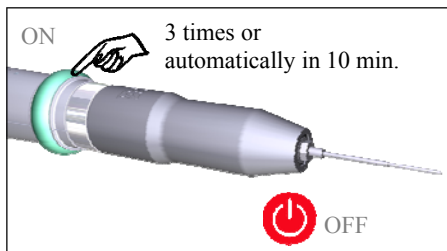


In the process of cooling the STATUS indicator on the handpiece **blinks LILAC**

At achieving the safe temperature of 50°C the STATUS indicator stops blinking and constantly lights **WHITE**.

Step 11. Power off

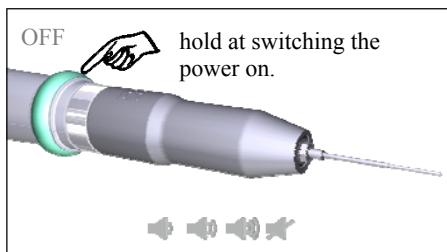
Press the ring switch 3 times to switch the power off or the device is switched off automatically in 10 minutes. All the LEDs on the handpiece go out.



Step 12. Audio volume adjustment

The handpiece acoustic emitter has 4 volume levels: low, normal, high and off.

To select the required volume level hold the ring switch when switching the power on. Within ~10 sec. volume levels change one another cyclically.

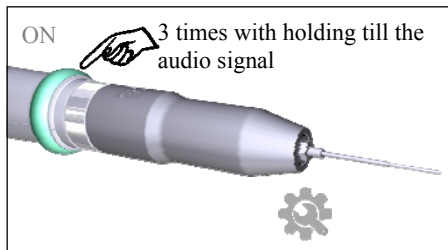


To choose the required volume level stop pressing the ring switch.

Step 13. Return to the factory settings

The handpiece settings could be changed at its joint work with the control unit “ESTUS MULTI”

To return to the factory settings of the handpiece:



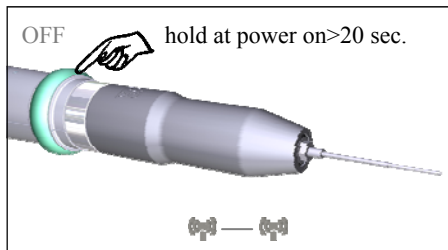
When the device is powered on, press the ring switch 3 times and hold it about 5 seconds after the device power is turned off. Release the button when the audio signal has sounded.

In this case, all settings will return to the factory values.

Step 14. Pair creation mode activation

For the joint work of the handpiece and the control unit “Estus Multi” by radio channel it is necessary to create a pair.

To activate pair creation mode on the handpiece:



Press and hold the ring switch at switching the power on. After 3 cycles of the audio signals with different intensity and 1 single audio signal (wait for 20 sec.) STATUS

indicator would constantly blink **WHITE**



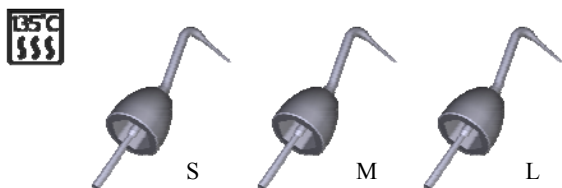
The pair creation further procedure of the handpiece with “Estus Multi” is described in the *User’s Manual “Estus Multi”* (p. 12.2. *Setting "Creating/Deleting pair" function*)

7. STERILIZATION AND DISINFECTION

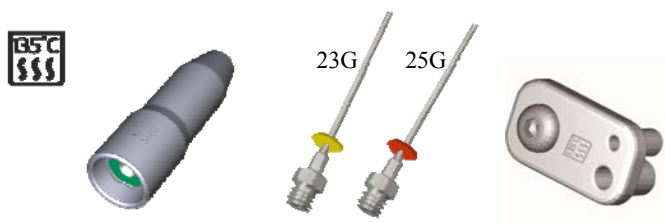
All the device's elements directly contacted with the patient's oral liquid, mucosa and tissues must be preliminarily cleaned and terminally sterilized. All the rest elements and surfaces of the device must be disinfected for further using without sterilization.

1. Preliminary cleaning and terminal sterilization

Sterilizable elements: thermopluggers S / M / L ,



The heater, injector needles 23G/25G and the multifunctional wrench for the injector needle.



The specified elements must be sterilized directly before the initial use of the device and between each patient use to avoid cross infection. Instruction on repeated sterilization and disinfection of the specified elements is in the tables 5-8



It is strictly forbidden to carry out any heat treatment (in an autoclave, dry heat sterilizer, glass bead sterilizers, etc.) of any other components of the product not listed in this paragraph.

Instruction on repeated sterilization and disinfection of reusable medical products

Instruction #1

Manufacturer: JSC Geosoft Dent (Russia)

Product: Thermopluggers S / M / L

Table 5

ATTENTION	
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is 250. In practice, the number of processing cycles is significantly higher, but depends on the regularity and quality of processing by the clinic personnel.
INSTRUCTIONS	
Place of use	Dental office and sterilization room.
Protection and transportation	No special requirements. It is recommended to use the product as soon as possible after the repeated processing .
Decontamination preparation	Not applied in this case.
Automatic cleaning/ disinfection	Not applied in this case.
Hand cleaning/ disinfection	Clean the metal surface of the product from gutta-percha residues with orange oil, and then wipe it with a clean napkin or a cloth soaked in a small amount of ethyl spirit.
Inspection, maintenance and testing	If the thermopluggers were very curved during use, try to straighten them without applying much effort

Table 5 continued

Packing	Recommended to pack the product in the craft package for sterilization.
Sterilization	Steam sterilizer (autoclave). Pressure – 0,2 MPa, Working temperature - $132\pm 2^{\circ}\text{C}$ ($270\pm 3^{\circ}\text{F}$). Sterilization time- 20 ± 2 min.
Drying	Not required
Keeping	To keep in a sealed craft package not longer than it is specified by the craft package manufacturer (from 21 to 60 days)

Instruction #2

Manufacturer: JSC Geosoft Dent (Russia)

Product: Injector needles 23G, 25G

Table 6

ATTENTION	The injector needles are autoclavable, but lose the passability of the injection channel during use. If the injector needle is worn, replace it with a new one.
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is 10. In practice, the number of processing cycles is significantly higher, but depends on the regularity and quality of processing by the clinic personnel.
INSTRUCTIONS	
Place of use	Dental office and sterilization room.
Protection and transportation	No special requirements. It is recommended to use the product as soon as possible after the repeated processing .
Decontamination preparation	Not applied in this case.
Automatic cleaning/ disinfection	Not applied in this case.

Table 6 continued

Hand cleaning/ disinfection	Clean the metal surface of the product from gutta-percha residues with orange oil, and then wipe it with a clean napkin or a cloth soaked in a small amount of ethyl spirit.
Inspection, maintenance and testing	Check the needle for damages and kinks; at the detection - replace the needle.
Packing	Recommended to pack the product in the craft package for sterilization.
Sterilization	Steam sterilizer (autoclave). Pressure – 0,2 MPa, Working temperature - $132\pm 2^{\circ}\text{C}$ ($270\pm 3^{\circ}\text{F}$). Sterilization time- 20 ± 2 min.
Drying	Not required
Keeping	To keep in a sealed craft package not longer than it is specified by the craft package manufacturer (from 21 to 60 days)

Instruction # 3Manufacturer: JSC Geosoft Dent (Russia)Product: Heater

Table 7

ATTENTION	It is forbidden to submit the product to ultrasonic cleaning with a disinfectant solution. Do not clean/disinfect the product by immersion in a washing / disinfecting solution. Sterilization of the product with the gutta-percha in the heater liner is forbidden.
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is 50. In practice, the number of processing cycles is significantly higher, but depends on the regularity and quality of processing by the clinic personnel.
INSTRUCTIONS	

Place of use	Dental office and sterilization room.
Protection and transportation	No special requirements. It is recommended to use the product as soon as possible after the repeated processing .
Decontamination preparation	It is necessary to remove all remaining gutta-percha from the heater liner.
Automatic cleaning/ disinfection	Not applied in this case.
Hand cleaning/ disinfection	Clean the shank end of the heater from gutta-percha residues with orange oil. Wipe the external surface of the heater with a clean napkin or a cloth soaked in a small amount of ethyl spirit. Do not immerse the product in a washing / disinfecting solution.
Inspection, maintenance and testing	Not applied in this case
Transportation	When sterilizing the product in a sterilization room, put it in any sterilized box to transport the product.
Packing	Recommended to pack the product in the craft package for sterilization.
Sterilization	Steam sterilizer (autoclave). Pressure – 0,2 MPa, Working temperature - 132±2°C (270±3 °F). Sterilization time-20±2 min. !!! To avoid the coating on the contact pads of the heater after sterilization, only distilled water should be used in the sterilizer
Drying	Not required
Keeping	To keep in a sealed craft package not longer than it is specified by the craft package manufacturer (from 21 to 60 days)
Preparation before re-use	To avoid worsening of the electrical contact of the heater after sterilization, wipe the heater pad with spirit before reuse.

Instruction # 4Manufacturer: JSC Geosoft Dent (Russia)Product: Multifunctional wrench for an injector needle

Table 8

ATTENTION	
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is 250. In practice, the number of processing cycles is significantly higher, but depends on the regularity and quality of processing by the clinic personnel.
INSTRUCTIONS	
Place of use	Dental office and sterilization room.
Protection and transportation	No special requirements.
Decontamination preparation	No special requirements
Automatic cleaning/ disinfection	Not applied in this case
Hand cleaning/ disinfection	Not applied in this case
Inspection, maintenance and testing	Not applied in this case
Packing	Recommended to pack the product in the craft package for sterilization.
Sterilization	Steam sterilizer (autoclave). Pressure – 0,2 MPa, Working temperature - 132±2°C (270±3 °F). Sterilization time-20±2 min.
Keeping	To keep in a sealed craft package not longer than it is specified by the craft package manufacturer (from 21 to 60 days)

Instruction # 1 - #4 were validated by the Manufacturer of the medical product as suitable for repeated using. The company, conducting the processing, is responsible for

repeated processing and for using the equipment, materials and the recruitment of the personnel providing the required result. The process must be validated and checked. Any procedure departures, declared in the instruction, must be estimated from the point of effectiveness and probability of possible adverse effects.

2. Disinfection.

The device elements, not contacted directly with the patient oral liquid, tooth tissues and mucosa during the treatment, must be disinfected for further using without sterilization.

Prior to disinfection of the used product, preliminary clean the contaminated surface.

Disinfection should be conducted chemically by wiping the product surface with thoroughly wrung napkin, soaked in 70% ethyl alcohol solution.



To avoid entering the disinfectant into the product housing, it is strictly forbidden to carry out disinfection by immersing the handpieces or the battery unit in any solutions.

8. MAINTENANCE

1. Replacing the thermoplugger of the “Estu Pack” handpiece

The Service time of the thermoplugger highly depends on the user.

Excessive bending or applying too much efforts to the thermoplugger significantly reduces its service life.

To increase the service life of the thermoplugger it is recommended:

- as carefully as possible to bend the thermoplugger, without putting a lot of effort;
- use the thermoplugger only as a tool for heat transfer and condensation of the heated gutta-percha. For compaction of cooled gutta-percha, it is recommended to use the standard manual “SSG Plugger” (Geosoft Endoline).

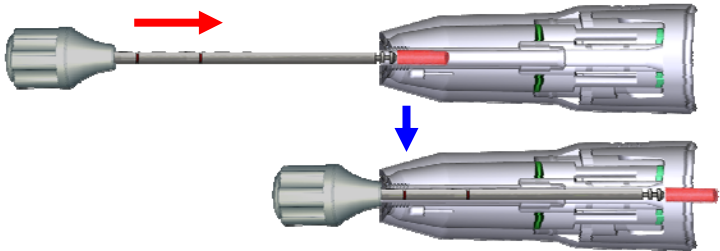
- Replace the thermoplugger in a timely manner if, at the heating mode activation the STATUS indicator on the handpiece blinks **RED** (*for more details, see section 6.1, Step 9*)

2. Cleaning the “Estus Fill” handpiece heater liner from gutta-percha

Cleaning the heater liner is necessary if it is required to partially or fully take out the gutta-percha from the heater liner without its heating and injecting (for example, if a new gutta-percha obturator was accidentally put on the top of the old one or if it is required to remove the gutta-percha residue from the liner before sterilizing the heater).



The heater must be cleaned only after cooling gutta-percha to indoor temperature.



A) Disconnect the injector needle from the heater and place the gutta-percha level measuring tool in the heater liner on the side of the needle holder.

B) Push the handle of the tool so that its metal part fully penetrates into the heater liner.

C) Remove the gutta-percha from the liner.

3. Cleaning the “Estus Fill” handpiece rod from the gutta-percha

Cleaning the rod from the gutta-percha residues is necessary if gutta-percha leaks beneath the gasket on the rod.

Carefully clean the rod from all gutta-percha residues with a gauze swab moisturized in orange oil.

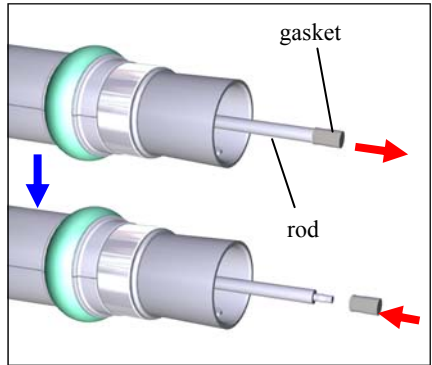



It is not recommended to use any mechanical cleaning of the rod, as this could lead to the rod and the gasket damage.

4. Replacing the gasket on the “Estus Fill” handpiece rod

In case of any mechanical damage of the gasket on the rod, the gasket should be replaced.

- A) Pull with a little effort and remove a damaged or worn gasket from the rod
 B) Take a new gasket and install it on the end of the rod by fixing it on the rod's herringbone.




 *Replaceable gaskets are not included in the delivery set and to be*


purchased separately additionally paid (see section 3 “Accessories”).

5. Battery unit maintenance

- Charge the battery unit in a timely manner. (see section 6, Step 1)
Do not let the battery unit discharge completely.
- Replace the battery unit timely when it depletes its working resource.

 *-For optimal battery unit performance, replace it about once every 2 years.*

- *It is not recommended to purchase an additional battery unit in advance, as during its long-term storage, the technical characteristics of the batteries deteriorate.*
- *An additional battery unit is not included into the delivery set and is purchased separately additionally paid (see section 3 “Accessories”).*

 *Do not dispose of the used battery unit in the household waste system. Dispose of the battery unit in accordance with the disposal regulations of the country in which this product is used.*

9. TROUBLESHOOTING

Table 9.

Problem	Possible cause	Solution
Handpiece does not switch on.	<ul style="list-style-type: none"> • The battery is discharged. 	<ul style="list-style-type: none"> • Charge the battery (<i>see section 6, Step 1</i>).
The battery unit charges too fast and/or the handpiece working time till the next charging is drastically reduced.	<ul style="list-style-type: none"> • The battery unit resource is depleted. The battery unit is not suitable for use. 	<ul style="list-style-type: none"> • Replace the battery unit.
The handpiece switches off spontaneously.	<ul style="list-style-type: none"> • Energy saving function activates. • The battery unit is discharged. 	<ul style="list-style-type: none"> • <i>See section 6.1, Step 5, section 6.2, Step 11</i> • Charge the battery unit.
The battery unit does not charge	<ul style="list-style-type: none"> • Bad contact between the battery unit, charger stand, cable, power adapter • Charging stand is failed • Charging cable is damaged. • Power adapter is defective. 	<ul style="list-style-type: none"> • Check connections • Replace the charging stand or Apply to the maintenance service • Replace the charging cable. • Replace the power adapter
Thermoplugger does not heat up to the set temperature. When heating mode is activated, the STATUS indicator blinks red.	<ul style="list-style-type: none"> • Thermoplugger is not installed in the handpiece. • Thermoplugger is failed or a non-original thermoplugger is installed. 	<ul style="list-style-type: none"> • Install the thermoplugger in the handpiece (<i>see section 6.1, Step 2</i>) • Replace the thermoplugger. Use only S, M, L thermopluggers (<i>see section 3</i>)

Table 9 continued


Problem	Possible cause	Solution
Sound problems	<ul style="list-style-type: none"> • Audio volume settings are incorrect 	<ul style="list-style-type: none"> • Check the settings (<i>see section. 6.1, Step 6, section 6.2, Step 12</i>)
Vibration in the thermopluggger heating mode is absent.	<ul style="list-style-type: none"> • The function is not provided in the chosen operating mode. 	<ul style="list-style-type: none"> • Choose mode PACK+  или MIX (<i>see section 6.1, Step 4</i>)
The heater fails to be fixed in the “Estus Fill” handpiece control unit.	<ul style="list-style-type: none"> • There is more gutta-percha in the heater liner than supposed (a new gutta-percha obturator is installed on top of the gutta-percha residues from the previous obturator) • A rod or a liner is contaminated by the gutta-percha residue. 	<p><i>Do not apply efforts!!!</i></p> <ul style="list-style-type: none"> • Disconnect the heater from the control unit and remove excess gutta-percha. If the gutta-percha obturator does not fall out of the liner itself, remove the gutta-percha using a special tool (<i>see section 8–2</i>). • Clean a rod or a liner from the gutta-percha residue (<i>see section 8–2,3</i>).
At the pushing the ring switch, no action occurs	<ul style="list-style-type: none"> • The heater is not installed. • The heater is not fixed. • Poor heater contact with the control unit. 	<ul style="list-style-type: none"> • Install the heater • Fix the heater by turning it clockwise • Wipe the heater pad and the handpiece terminals with spirit.
Gutta-percha is not heated. The battery unit charge indicator lights orange or red.	<ul style="list-style-type: none"> • The battery is discharged. 	<ul style="list-style-type: none"> • Charge the battery (<i>see section 6, Step 1</i>).

Table 9 continued.

Problem	Possible cause	Solution
Gutta-percha is not heated - the STATUS indicator first blinks orange and then red.	<ul style="list-style-type: none"> • Poor heater contact with the control unit. 	<ul style="list-style-type: none"> • 1. Wipe the heater pad and the handpiece terminals with spirit. • 2. Check the failure of the bayonet connector of the heater; if it is damaged, replace the heater with a new one.
Gutta-percha is poorly pressed out of the injector needle.	<ul style="list-style-type: none"> • Needle problems (too strong bending, clogging). • The battery is discharged. 	<ul style="list-style-type: none"> • Replace the injector needle. • Charge the battery (<i>see section 6, Step 1</i>).
Gutta-percha is not pressed out of the injector needle.	<ul style="list-style-type: none"> • The working temperature is not achieved. • The gutta-percha extruding out of the needle is delayed because of using the new needle. • The injector needle fracture 	<ul style="list-style-type: none"> • Wait until the STATUS indicator stops blinking and would lit up orange and try again. • Press and hold the ring switch until the gutta-percha appears on the tip of the needle • Replace the injector needle.
Gutta-percha leaks onto the rod underneath the gasket	<ul style="list-style-type: none"> • The rod is contaminated with the gutta-percha residue. • The gasket damage on the rod. 	<ul style="list-style-type: none"> • Clean the rod of the gutta-percha residue (<i>see section 8-3</i>). • Replace the gasket (<i>see section 8-4</i>).

Table 9 continued.

Problem	Possible cause	Solution
Gutta-percha is squeezed out of the injection needle too slowly/too fast	<ul style="list-style-type: none"> The level of the gutta-percha extrusion rate is incorrectly configured 	<ul style="list-style-type: none"> Check the settings (see p. 6.2 (Step 7))

If you have not found the necessary information, You may consult the manufacturer on the phone: +7(495)663-22-11 (extension 109), E-mail: geosoftdent@geosoft.ru or address to the service department

10. STORAGE, TRANSPORTATION AND USE

- The product should be stored in heated and ventilated place at temperatures from + 5°C to + 40°C, with a relative humidity of 80% (at + 25°C), in the original packaging of the manufacturer.
- The product should be transported by any type of covered vehicles at temperatures from -50°C to + 50°C with a relative humidity of not more than 100% (+25°C) in the original packaging of the manufacturer.
- The product should be used in heated and ventilated place at temperatures from + 10°C to + 35°C, with a relative humidity of not more than 80%, at atmospheric pressure (101 ± 3) kPa













11. INFORMATION ON UTILIZATION

! It is strictly forbidden to dispose of the used product in the household waste system. Dispose of the product in accordance with the disposal regulations of the country in which this product is used.



The device ESTUS PACK-FILL belongs to the medical waste hazard category of class A (non-hazardous waste of medical institutions).

12. SYMBOL DESCRIPTIONS

Symbol	Description
	Warning: Address to supporting documentation
	Type of protection against electric-shock hazard. Device of the II class
	Direct current
	Protection level from electrical shock: Applied part B type
	Do not throw away the device into system of daily rubbish
	The device serial number
	Date of the device manufacturing
	Manufacturer
	Non-ionizing radiation sign - the product contains a radio frequency transmitter
REV.	The device revision version
IP41	Ingress Protection Rating dust and moisture
	Consult the USER'S MANUAL
	European authorized representative
	Mark of conformity to product quality and safety standards of the European Union (CE-mark)

APPENDIX

1. Electromagnetic Emissions and Immunity

Table 1

<p>The device «Estus Pack-Fill» is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</p>		
Emission test	Conformity	Electromagnetic environment - guidance
RF Emissions CISPR11	Group 1	The device «Estus Pack-Fill» uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Class B	It is possible to use the device «Estus Pack-Fill» in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable	

Table 2

<p>The device «Estus Pack-Fill» is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</p>			
Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
<p>Electrostatic discharge (ESD) EN 61000-4-2</p>	<p>± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air</p>	<p>± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air</p>	<p>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</p>
<p>Burst/Fast Transient EN 61000-4-4</p>	<p>±2 kV for power supply lines ±1 kV for input/output lines</p>	<p>±2 kV for power supply lines ±1 kV for input/output lines</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Surge EN 61000-4-5</p>	<p>±0,5; ±1.0; ±2.0 kV for scheme «line-to-ground» ±0,5; ±1.0 kV for scheme «line-to-line»</p>	<p>±0,5; ±1.0; ±2.0 kV for scheme «line-to-ground» ±0,5; ±1.0 kV for scheme «line-to-line»</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>

Continuation of Table 2

Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<u>Voltage dips:</u> 0% U_T for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 70% U_T for 25/30 cycles (at 0°) <u>Voltage interruptions:</u> 0% U_T for 250/300 cycle	<u>Voltage dips:</u> 0% U_T for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 70% U_T for 25/30 cycles (at 0°) <u>Voltage interruptions:</u> 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device «Estus Pack -Fill» requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field of power frequency (50Hz) EN 1000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T - level mains voltage prior to filing of the test exposure			

Table 3

The device «Estus Pack-Fill» is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
RF conducted EN 61000-4-6	3 V from 150 kHz to 80 MHz	3 V from 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device «Estus Pack-Fill», including cables, than the recommended separation distance calculated from that equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ (from 150 kHz to 80 MHz)
RF radiated EN 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	3 V/m from 80 MHz to 2.7 GHz	$d = 1,2 \sqrt{P}$ (from 80 MHz to 800 MHz) $d = 2,3 \sqrt{P}$ (from 800 MHz to 2.7 GHz) where: P - the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d - the recommended separation distance in meters (m)


Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 4

Recommended working clearances between portable and mobile RF communication devices and the device «Estus Pack-Fill»			
The device «Estus Pack-Fill» is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	from 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	from 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	from 800 MHz to 2,7 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0.23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

2. Information on the availability in the medical device of a pharmaceutical product for medical use, materials of animal and (or) human origin

<i>Materials in the device</i>	<i>Description (if they are)</i>
Pharmaceutical product for medical use	Gutta-percha obturators (Diadent Group International)
materials of animal and (or) human origin	absent

3. The list of european standards used by the manufacturer of the medical device

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 61000-4-2:2009, EN 61000-4-3:2020, EN 61000-4-4:2012, EN 61000-4-5:2014, EN 61000-4-6:2014, EN 1000-4-8:2010, EN 61000-4-11:2020, CISPR 11(2019), EN 80601-2-60:2015, EN ISO 14971:2019/A11:2021, EN 62304:2006/A1:2015, EN ISO 10993-1:2020, EN ISO 10993-2:2006, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-9:2021, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, MEDDEV. 2.7.1 Rev.4, MEDDEV 2.12-1 rev.8, MEDDEV 2.12/2 rev.2, EN ISO 15223-1:2021, EN ISO 17664:2004, EN ISO 17665-1:2006, RoHS 2011/65/EU, EN 62353:2014, RED 2014/53/EU

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